

structure or tube. With specific regard to supporting structure at the bottom of column 6 and top of column 7 in '492 the preferred form is woven fabric for the hollow tube, track-tube, or hollow-flat-tube having finished longitudinal edges. The internal filler is to shape the woven tubes and may or may not remain therein during use. Throughout '492 the drain is referred to as a tube like channel. No disclosure of the filler without the woven support is presented as that would be contrary to the design and use of that drain.

As set forth in great detail in Applicant's application as filed including the figures, description and claims and as supported and explained in the affidavit of the inventor, John B. McCraw herewith submitted the flexible fibers are the drain. No tubing or supporting structure is required or used to hold the flexible fibers inside the patient or hold the exit open or contain the flexible fibers where they pass through the skin. Notwithstanding that the Applicant's drain is effective and less traumatic as set forth in the affidavit. Reference '492 has the woven supporting structure or tube to contain the filler cord where it passes through the skin and keep it apart from the patient; that is exactly opposite what Applicant has done.

The Examiner rejects Applicant's claims 2 and 10 on '492 as having a surgical tube having a discharge for attaching to vacuum. Again Applicant's figures 3 through 12 and 14 have no tube passing from inside the patient to the outside for vacuum. The Applicant's flexible fiber drain has an external collector to which the vacuum may be applied. In fact and as shown in the photos submitted with the affidavit the collector can be a simple piece of cotton or gauze. No supporting structure or tube passing through the tissue is required with Applicant's flexible fiber drain. Applicant has added the term, "external" to every occurrence of collector in the claims and that is amply supported in the figures and description as filed. The Examiner has cited a tube that passes from inside to outside as the same as Applicant's flexible fiber drain and external collector; as explained those are not the same and '492 does not suggest what Applicant has done.

The Examiner rejects Applicant's claims 3, 4, 11, and 12 as having a woven drain with polyester and Nylon filaments. Applicant's claimed flexible fibers are not

woven and have no structure *per se* so that they may easily spread out within the patient's surgery and extend through a small or minimal exit opening through the tissue to the external connector. That is quite different from that disclosed in the '492 reference. The use of existing materials in a new and unobvious construction is patentable as an apparatus and in methods as claimed.

The Examiner rejects Applicant's claims 5 and 13 on '492 as having absorptive filler material. Applicant's flexible fibers may be absorptive but they also might simply guide the drainage from the surgery with or without capillary action, absorption or simply surface attraction along the flexible fibers; exactly how they work is not the issue as the affidavit makes clear they perform well and without any tube or supporting structures where the fibers pass through the patient's tissue.

The Examiner rejects claims 6, 7, 14 and 15 on '492 as having drain fabric treated with antimicrobial and antithrombogenic agents. Applicant has no fabric *per se* but does dependently claim antimicrobial and antithrombogenic fibers in a drain construction not disclosed or suggested in '492.

The Examiner rejects Applicant's claims 21 and 22 on '068 as teaching a gravity drainage cord formed by braiding a plurality of strands inserted loosely into a silicone **tubular sheath** that also allows connection to aspiration (emphasis added). No disclosure of an unbraided and/or unsupported drain made of flexible fibers is suggested or described as that would be contrary to the design and use of the '068 drain. As set forth in great detail in the application as filed including the figures, description and claims and as supported and explained in the affidavit of the inventor, John B. McCraw submitted herewith the flexible fibers are the drain; no supporting structure or tubing is required or used to hold the exit opening or contain the flexible fibers inside the surgical site or where they pass through the skin. Notwithstanding that the claimed drain of Applicant is effective and less traumatic as set forth in the affidavit.

Applicant addressed the teachings of the references submitted with the filing of the application. Please see the portions of the application reproduced below.

“Recent United States Patent 6,605,058 has a gravity drainage cord formed by braiding a plurality of strands of silk of the type used for surgical sutures, and fitted or assembled loosely, in the median region, in a tubular sheath made of a material such as silicone. The outer silicone tube facilitates sliding of the assembly with respect to tissue, increases biocompatibility and allows optional coupling to mechanical aspiration units. Capillary action is said to be the mechanism of drainage. The protrusion of the cord into the wound allows small movement and if more than one cord is used some distributing and spreading are taught to increase drainage. Inside the cavity to be drained the tube may have radial holes to facilitate drainage. **No use of the cords without the tube is acceptable and no mechanism other than capillary action is disclosed.** The disclosure of Patent 6,605,058 is incorporated by reference and made a part of this background. (Emphasis added)”

From the application as filed the wound or surgical opening is the exit opening through the patient’s skin as shown and described in the application:

“The flexibility and adaptability of the plurality of fibers 12 also accommodated the form or shape of wound or surgical opening 16 that can take many contours as previously explained. The referenced prior patents and drainage devices do not have or perform the feature of spreading out within the wound or surgical site.”

The affidavit includes evidence that drain flexibility and fibers that guide and direct flow along, among and about each flexible fiber is how it works. That flexibility permits the fibers to spread out and collect the drainage and allow the healing of the exit opening about the flexible fibers with minimal trauma. Data, test results, observations and insight on how the claimed drain functioned in experimental trials after surgery and why it performed better is included. Quantification of the merit of the flexible fiber drain is also provided. The clinical tests support the way in which the claimed drain works and its resistance to clogging, faster healing, less trauma, etc.

The prior patents considered individually or combined fail to teach the specifically claimed elements that are unique to the invention and unknown in ‘058 and ‘068. For example in Applicant’s claim 1 the recitation of the following:

“...each fiber elongate with a thickness and a length wherein its thickness is substantially less than its length for flexibility, the plurality of

fibers having gathered together external ends leaving the internal ends unrestrained to spread out; ...
the plurality of fibers flexible so that at their unrestrained internal ends each fiber is able to spread divergently of the other fibers while inside the wound or surgical site.”

The language, “inside the wound” is a direct reference in the claim as filed to the exit opening which make it clear that the geometry of the fibers relates specifically to their flexibility and assures each unrestrained fiber passes freely through the tissue and skin.

Likewise in method claim 9 the steps of:

“...providing a plurality of fibers each having an internal end, an external end and a middle there between, each fiber elongate with a thickness and a length wherein its thickness is substantially less than its length for flexibility;...
allowing the internal ends to remain unrestrained for spreading within the wound or surgical site a plurality of fibers each having an internal end, an external end and a middle there between, each fiber elongate with a thickness and a length wherein its thickness is substantially less than its length for flexibility;...
guiding bodily fluid along and amongst the fibers from the internal ends along the middle and to the gathered together external ends during drainage of fluid from a wound or surgical site;
positioning an external collector in fluid communication with the gathered together external ends and percutaneously covering the wound or surgical site opening...”

Those steps were not suggested or disclosed and thus the method Applicant claims as new and unobvious.

Claim 21 recites the method of manufacture and placement of Applicant’s drain not specifically taught or suggested by the reference(s).

“gathering together each fiber elongate with a thickness and a length wherein its thickness is substantially less than its length for flexibility at their external ends while leaving the internal ends unrestrained, and positioning an external collector in fluid communication with the gathered together external ends for accumulating bodily fluid guided along, about and amongst the fibers from the internal ends along the middle and to the gathered together external ends during drainage of fluid from inside the wound or surgical site.”

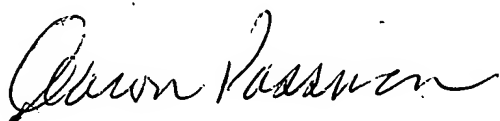
Again the fiber flexibility due to the claimed length thickness relationship and the spreading in the wound or surgical site are in the claimed steps.

The amended claims have minor clerical corrections in claims 9 and 22.

DeCarlo is a new reference cited against claims 8 and 16. The Applicant's claimed particulars on vacuum applied to drainage are dependent upon the flexible fibers passing through the tissue at the wound or exit opening that is not in DeCarlo or any of the references.

Examiner can not and should not maintain the rejections on the references, without at least finding a disclosure of a drain without any tubing or supporting structure about flexible fibers where they pass through the skin, to do so would be premature. The claims have been corrected and clarified, the references distinguished and the Applicant has submitted an affidavit and benefit of his drain of flexible fibers. Should there be any questions, the Examiner is encouraged to call or email the Applicant's undersigned attorney.

Respectfully submitted on behalf of Applicant and for prompt allowance,

A handwritten signature in cursive script, reading "Aaron Passman".

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